REMARKS

The Final Office Action dated January 20, 2010 and the Advisory Action dated June 17, 2010 has been carefully considered. Claims 1, 7, 9 and 13 have been amended. Claims 6, 11, 14-16, 33, 36 and 38 have been canceled. Claims 1, 2, 7, 9, 11, 13, 22, 24-27, 30, 34 and 35 are in this application.

In the Advisory Action the Examiner indicated that the amended claims were indefinite. Applicant has amended claim 1 to obviate the Examiner's objection.

The previously presented claims 1, 2, 9-11,13, 22, 24, 25, 27 and 30 were rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,405,613 to Rowland, as evidenced by U.S. Patent No. 6,440,436 to Ghosal ("Ghosal '436"), Janjua (Hamdard Medicus 1991) and U.S. Patent No. 6,124,268 to Ghosal ("Ghosal '268").

Claim 1 has been amended to include the limitations of claim 6. Accordingly, Rowland Ghosal '436, Janjua and Ghosal '268 do not include each of the limitations of the present claims and the invention defined by the present claims is not anticipated by the cited references. Withdrawal of this rejection is respectfully requested.

The previously submitted claims were rejected under 35 U.S.C. § 103 as obvious in view of Janjua and Ghosal '268 or Rowland in combination with EP0037144 to Riley.

The invention defined by the present claims is directed a phenolic antioxidant-chromium complex wherein the phenolic antioxidant is a hydrolyzable tannin from Phyllanthus emblica in which the chromium is Cr(III) and the chromium content in the complex is from 0.01 to 20% of the complex. It has been found that Cr(VI) induces oxidative stress, DNA damage, apoptotic cell death and altered gene expression. Cr(III) in absence of antioxidants is converted to chromium (VI). The invention defined by the present claims provides a complex having sufficient chromium content that can be used for treating hyperglycemia. None of the cited references teach or suggest the invention defined by the present claims.

Rowland teaches at col. 4, lines 41-50 that

> "The extracted Shilajit is then treated with a mixture of three herbs known as trifla, which includes amla (*emblica officinalis*), bahera (*terminalia chebula*), and haritaki (*terminalia belerica*), to remove possible contaminants. The purified Shilajit which is obtained is then dehydrated to remove moisture. The Shilajit

> produced and refined by this method is almost totally sterile. Laboratory analysis reveals that it has a bacterial count of only 50 colonies per gram and a yeast-/fungus count of only 10 colonies per gram".

In contrast to the invention defined by the present claims, Rowland does not teach or suggest a phenolic antioxidant-chromium complex wherein the phenolic antioxidant is a hydrolyzable tannin from Phyllanthus emblica in which the chromium is Cr(III) and the chromium content in the complex is from 0.01 to 20% of the complex. Instead, Rowland teaches that Shilajit is treated with Phyllanthus emblica for the purpose of removing possible contaminants to obtain "purified Shilajit". However, Rowland does not teach or suggest a phenolic antioxidant-chromium complex wherein the phenolic antioxidant is a hydrolyzable tannin from Phyllanthus emblica.

Janjua teaches heating the *Phyllanthus emblica* herb at 1200°C for 16 hours to obtain the ash. Measurements of atomic absorption of the ash were used to obtain the concentration of chromium. However, Junjua does not teach or suggest a phenolic antioxidant-chromium complex wherein the phenolic antioxidant is *Phyllanthus emblica*, as defined by the present claims. In addition, Junjua does not teach or suggest the chromium content in the complex is from 0.01 to 20% of the complex and do not cure the deficiencies of Rowland noted above.

Ghosal '268 teaches a process for producing an antioxidant blend from *emblica officinalis* fruit. As noted by the Examiner, Ghosal '268 does not teach an antioxidant-chromium complex. In addition, Ghosal '268 does not teach or suggest the chromium content in the complex is from 0.01 to 20% of the complex and do not cure the deficiencies of Rowland and Janjua noted above.

Riley discloses the use of chromium(III) non-acetylacetonate complexes as a dietary supplement. Single dosage amounts range from 0.15 to 100 micrograms of chromium complex per kg of body weight. In contrast to the invention defined by the present claims, Riley does not teach or suggest a phenolic antioxidant-chromium complex wherein the phenolic antioxidant is *Phyllanthus emblica*. Instead, Riley is directed to chromium(III) non-acetylacetonate complexes. In addition, Riley does not teach or suggest the chromium content in the complex is from 0.01 to 20% of the complex. The dosage amounts in Riley are directed to amounts of the chromium complex per kg of body weight and not to the amounts of chromium content in the complex.

There is no teaching or suggestion in Riley of the amounts of chromium content in the complex. Accordingly, Riley does not cure the deficiencies of Rowland, Janjea, and Ghosal '268 noted above.

The present invention provides unexpected results in the form of showing substantially improved effect when an external source of chromium is mixed with a *Phyllanthus emblica* antioxidant fraction to form a phenolic antioxidant-chromium complex over the results obtained merely from the effect of providing *Phyllanthus emblica* alone. At Example 4 of the Application (pages 29-30), an experiment is presented where mice were made diabetic by injection with streptozocine and then were treated with *Phyllanthus emblica* alone or with *Phyllanthus emblica* with exogenous chromium in the form of phenolic antioxidant-chromium complex. The results in Table 1 show that while *Phyllanthus emblica* extract at 10 mg/kg or 20 mg/kg prevents high serum glucose by 22 or 28% inhibition, respectively (N-1 and N-2), treatment with *Phyllanthus emblica* phenolic antioxidant-chromium complex produced a 58% inhibition of high serum glucose (N-3). Thus, the results provided in the Application provide a showing of unexpected results that were not taught or suggested in any of the references or their combination.

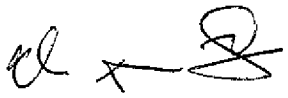
Obviousness-Type Double Patenting

Claims 1, 14, 15, 22, 33 and 36 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 1 and 2 of Ghosal '436 and claim 1 and 7 of U.S. Patent No. 6,869,612 to Ghosal ("Ghosal '612").

Without acquiescing to the correctness of this rejection, in order to advance prosecution, Applicant will file a Terminal Disclaimer at such time as agreement is reached that the claims are otherwise in condition for allowance, if at that time, the form of the claims has not been appreciably amended so as to remove the claims from the obviousness-type double patenting rejection.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,



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